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January 16, 2018

Demetrios Kouzoukas

Principal Deputy Administrator for Medicare and Director Center for Medicare

Hubert H. Humphrey Building 200 Independence Avenue, S.W Washington, DC 20201 Submitted electronically

Attention: CMS-4182-P

**Re:** Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Dear Principal Deputy Administrator Kouzoukas:

MAXIMUS, Inc. appreciates the opportunity to share our comments on the Centers for Medicare & Medicaid Services' (CMS) policy and technical changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. MAXIMUS currently serves as the Qualified Independent Contractor (QIC) for the Part A West Jurisdiction and the Part C and Part D Independent Review Entities (IRE).

MAXIMUS employs full-time medical directors, health attorneys, pharmacist-attorneys, nurse- attorneys, nurse professionals and podiatrist-attorneys. Our fully credentialed national panel of more than 1,000 physicians and other reviewers represent every recognized medical specialty and all major licensed practitioner categories. Today we receive more than 200,000 appeals claims a year for Medicare Parts A, C, and D.

Appeals of Prescription Drug Lock-in

As directed by the Comprehensive Addiction and Recovery Act of 2016 (CARA), in the proposed rule, CMS describes the framework under which Part D plan sponsors may establish a drug management program for beneficiaries at-risk for prescription drug abuse by locking them into a particular prescriber or pharmacy. Plan sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs." CMS is proposing that at-risk beneficiaries (or an at-risk beneficiary's prescriber, on behalf of the at-risk beneficiary) must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. An adverse redetermination would not be

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automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication timeframe.

MAXIMUS does not agree with the CMS's interpretation of the CARA language on appealing a lock-in and believes auto escalation would ensure beneficiary due process and access to needed prescription drugs. While the Part D appeals process does not include the auto-escalation of benefit denials to the IRE, MAXIMUS has found the lack of auto-escalation is a significant barrier to the entire Part D appeals process, burdening the Part D enrollees with red tape and hindering their access to Part D drugs.

CARA1 requires the initial beneficiary notice of lock-in to include information on "the option of an automatic escalation to external review." As explained further in the same statutory provision, this is "(similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act that allow an automatic escalation to external review of claims submitted under such part)." CMS has instead proposed to provide "the right to a reconsideration or expedited reconsideration" to the IRE. Expedited appeals provide for shorter time frames for consideration and action on an appeal of a plan decision. It is very different than auto escalation that provides for an automatic independent review of a plan's negative decision on a beneficiary's appeal of a lock-in.

Additionally, the lack of auto-escalation increases the timeframe for the lock-in appeals process. CMS has proposed to add case-management and physician agreement when a beneficiary is at risk for prescription drug abuse. While MAXIMUS applauds these patient protections, they create additional hurdles and delays for patients who are not at-risk and do need the "frequently abused drugs". Auto-escalation to the IRE would ensure that there are no further delays in considering the appeals of the locked-in status.

Furthermore, plans have a poor record of complying with current requirements for timely appeals. CMS audits2 of Part C and Part D plan sponsors found that, after not having disposed of the appeal in the required time at the plan level, the sponsors do not auto-forwarded to the IRE as required in the required timeframe either. This "non-compliant condition" is described as "Sponsor did not appropriately auto-forward coverage determinations and/or redeterminations (standard and/or expedited) to the Independent Review Entity (IRE) for review and disposition within the CMS required timeframe." This non-compliant condition has been present in 5 of the 7 years CMS has conducted the audits. Of the plans audited in 2015 and 2106, 22 plans of 54 (or 41%) were found to be out of compliance with this basic beneficiary protection. As some plan sponsors are not considering redeterminations in a timely fashion and not currently auto- forwarding the appeals they do not complete according to CMS timelines, the lack of auto- escalation delays the appeals process further, thus infringing on beneficiary's right to due process.

A lock-in is a significant curbing of a beneficiary's rights to choose their pharmacy and their physician and requires nothing less than an automatic reconsideration by the IRE when the plan

1 Public Law No: 114-198, SEC. 704. PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER

MEDICARE PARTS C AND D (a) Drug Management Program for At-Risk Beneficiaries

2 2016 Part C and Part D Program Audit and Enforcement Report

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has denied a beneficiary's appeal of their locked-in status. **We urge CMS to implement the law as written and auto-escalate a locked-in beneficiary's appeal of a plan's negative decision to lock them in to a single provider and/or pharmacy.**

Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE

CMS is proposing that when a Medicare Advantage plan sponsor auto-escalates an adverse or partially adverse decision to the IRE, the plan would no longer have to notify the enrollee that the decision has been sent to the IRE. CMS notes that the IRE contractually must notify the enrollee that they have received the case, so having the plan sponsor do it is duplicative and nonessential.

MAXIMUS agrees that the process is duplicative and supports CMS's efforts at paperwork reduction. However, in addition to being part of the IRE's contract, this notification is also included in the CMS Model Notice of Appeal Status3 that plan sponsors send to the appellants after adjudicating the redetermination. The Model Notice includes language regarding next steps:

**What happens next?** Medicare requires us to send your case to MAXIMUS Federal Services, Inc. to make sure we made the right decision. MAXIMUS is an independent reviewer. You have the right to submit additional information that may be important to the review. MAXIMUS will contact you soon to let you know where to send any additional information and about other rights you may have.

As this language is included in the plan sponsors' notices, it is redundant for the IRE to send a notice to the beneficiary announcing receipt of the auto-escalated case. However, CMS does not propose to eliminate the Notice of Appeal Status affirming the plan's previous adverse or partially adverse coverage decision. Additionally, it could be confusing for the beneficiary to receive a notice from the IRE, with whom the beneficiary has no previous interaction, instead of receiving a notice from the plan sponsor, from whom the beneficiary is awaiting the appeal redetermination decision. Therefore, **we urge CMS to continue to include the notice of auto- escalation in the plan sponsors' Notice of Appeals Status and instead eliminate the IRE's contractual obligation to notify the beneficiary of receipt of the escalated appeal.**

Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

CMS proposes to change to the adjudication timeframe for Part D standard redetermination requests for payment from 7 calendar days to 14 days. This will allow plan sponsors to gather any missing information and reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE when the plan does not make a redetermination within 7 days.

3 Medicare Managed Care Manual, Chapter 13, §10.3.3, 80.3, and Appendix 10. Model Notice of Appeal Status (Rev. 105, Issued: 04- 20- 12, Effective: 04 -20- 12, Implementation: 04- 20- 12).

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CMS also proposes to increase the timeframe for IRE reconsideration from 7 to 14 days. MAXIMUS agrees with this proposed change as it would better align with the appeals process in commercial health plans and create a more beneficiary-friendly environment. The IRE does not have direct access to Part D plans' claims history or the health plans' proprietary systems when as if often the case, this information is not always forwarded to the IRE with the appeal. The additional time will allow the plan sponsor and/or the IRE to gather all pertinent claims and medical record data for this retrospective payment.

Because the beneficiary has received the prescription, the additional time does not needlessly delay access to the treatment. Additionally, it relieves burdens on the beneficiary to quickly provide additional information to the IRE. As a result, the additional time will allow the IRE to develop a more complete and accurate explanation of the reconsideration decision.

This proposal could also reduce the number of reconsiderations that the IRE does not find in favor of the beneficiary due to insufficient information. Currently, if all pertinent information is not obtained within the 7-day timeframe, the IRE will likely issue an unfavorable decision. If the beneficiary is able to obtain the missing information to file a reopening of the appeal, the IRE has 120 days to make a finding. Subsequently, the beneficiary could escalate the appeal to the Office of Medicare Hearings and Appeals' Administrative Law Judges. The current wait time for pending beneficiary appeals at OMHA from the Part D IRE is 35.8 days with an additional 21.9 days for the decision to be issued4.

Allowing the plan and the IRE additional time to gather all relevant information will reduce the burden on the enrollee and result in a more complete and accurate reconsideration decision.

Therefore, **MAXIMUS supports the proposal to expand the adjudication timeframe for Part D payment redeterminations and IRE reconsiderations to 14 days each.**

Thank you for your consideration of our comments. We look forward to working with CMS to ensure that the appeals process for Medicare managed care programs protect beneficiary due process while safeguarding Medicare resources. Please contact me if you have questions or feel free to have a member of your team contact Patrick Pinell (patrickpinnell@maximus.com) or Brian Isaac (BrianIsaac@maximus.com).

Sincerely,



Thomas Naughton President, Health Division MAXIMUS Federal

4 OMHA, Beneficiary Appeals Data, [https://www.hhs.gov/about/agencies/omha/about/current-](https://www.hhs.gov/about/agencies/omha/about/current-workload/beneficiary-appeals-data/index.html) [workload/beneficiary-appeals-data/index.html](https://www.hhs.gov/about/agencies/omha/about/current-workload/beneficiary-appeals-data/index.html).; accessed January 8, 2017.

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